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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/419,305

10/15/99

MARUTA

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WASHINGTON DC 20004

HM22/0522

EXAMINER

PROUTY, R

ART UNIT

PAPER NUMBER

1652

DATE MAILED:

05/22/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

Office Action Summary

Application No.
09/419,305

Applicant(s)
Maryta et al.

Examiner
R bec a Prouty

Art Unit
1652



-- Th MAILING DATE of this communication appears n the cov r sh et with the corresp ndence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on Feb 26, 2001

2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1 is/are pending in the applica

4a) Of the above, claim(s) _____ is/are withdrawn from considera

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) 1 is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirem

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. _____

3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

19) ☐ Notice of Informal Patent Application (PTO-152)

17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

20) ☐ Other: _____

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The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 1 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 5,976,856. Although the conflicting claims are not identical, they are not patentably distinct from each other because each recite variants of the enzyme of SEQ ID NO:1.

Applicant's request to hold this rejection in abeyance until a notification the claims are otherwise allowed is noted but the rejection will be maintained until a disclaimer is filed or the rejection is otherwise overcome.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and

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distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite and confusing in the recitation of "said amino acid sequence comprising the sequence of one or more fragments of SEQ ID NO:3 and SEQ ID NO:4" as it is unclear if this means the sequence must contain both SEQ ID NO:3 and SEQ ID NO:4, either of SEQ ID NO:3 or SEQ ID NO:4, or only some fragment of one or both of these sequences. If the last of these is intended, this recitation has essentially no meaning as all proteins are comprised of amino acids and will contain at least one amino acid residue that is found in SEQ ID NO:3 or SEQ ID NO:4. It is suggested that this be amended to read either "said amino acid sequence comprising the sequence of SEQ ID NO:3 or SEQ ID NO:4" or "said amino acid sequence comprising the sequence of SEQ ID NO:3 and SEQ ID NO:4" depending on applicants' intent.

Claim 1 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the enzyme of SEQ ID NO:1 or enzymes encoded by genes which will hybridize to SEQ ID NO:2 under specific conditions, does not reasonably provide enablement for any enzyme with the claimed properties. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected,

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to make the invention commensurate in scope with these claims.

The rejection is explained in the previous Office Action.

Applicants argue that the defined properties allow the skilled artisan to readily find other such enzymes by screening other microorganisms for those with the recited activity and further screening those with activity for the other recited characteristics.

First, it should be noted that the specification does not teach an assay for the activity recited in part (1) of the claim which would be easy to use for screening large numbers of organisms. The activity assay of pages 13-14 requires an HPLC separation of the products of the reaction which is difficult to use for large scale screening. Furthermore, while the number of naturally occurring enzymes which meet all of these claimed properties (activity, molecular weight, pI, and thermostability) may not be enormous (although it could be a fairly substantial number as it is certainly not uncommon for enzymes with related activities to be similar in other properties as well as they are often evolutionarily related to each other), applicants claims are not limited to naturally occurring enzymes but also include all non-naturally occurring variants and fragments of such naturally occurring enzymes which retain the claimed physicochemical properties. This group clearly is enormous.

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Furthermore, while the skilled artisan could readily make variants of the enzyme of SEQ ID NO:1 by using known mutagenesis techniques, such techniques would be sufficient for one of ordinary skill in the art to make and use variants with only a few substitutions by making several variants and testing for those which retain the claimed properties. Such experimentation would clearly be undue for those polypeptides with greater numbers of substitutions as the likelihood of a variant sequence retaining the claimed properties of the native polypeptide decreases substantially with each additional mutation while the number of possible variants which could be made increases exponentially. As such the claimed variants (i.e., those which retain the claimed physicochemical properties of the native polypeptide) with larger numbers of mutations are a very minute fraction of the possible variants which could be made and the experimentation required to make and test all the possibilities would clearly be undue.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of

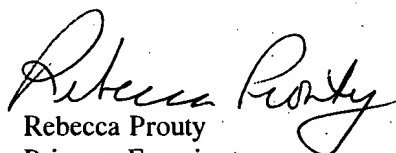
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the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rebecca Prouty, Ph.D. whose telephone number is (703) 308-4000. The examiner can normally be reached on Monday-Friday from 8:30 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy, can be reached at (703) 308-3804. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.


Rebecca Prouty
Primary Examiner
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